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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,204	06/20/2001	Lawrence Restaino	536-3	4612

7590 10/22/2003  
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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/885,204	<b>Applicant(s)</b> RESTAINO, LAWRENCE	
	<b>Examiner</b> Jon P Weber, Ph.D.	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 15 August 2003.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-10 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a)  All    b)  Some \*    c)  None of:  
    1.  Certified copies of the priority documents have been received.  
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .  
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other:   |

***Status of the Claims***

The response with amendments filed 15 August 2003 has been received and entered. Claims 1-10 have been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jon P Weber, Ph.D.

***Specification***

The disclosure stands objected to because of the following informalities: There are still several misspellings of "galactopyranoside", e.g., pages 2, 4, 5, for example.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are now rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 now recites that, "some non-target bacteria react with the first substrate but not the second substrate and other non-target bacteria react with the second substrate but not the first substrate". Implicit support for this new limitation is alleged at the paragraph bridging pages 9-10, which recites in part, "Non-target bacteria are positive with respect to one or both substrates."

First, the term "substrate" is not clear. The same term is used different ways and is not well defined in this instance. Regardless, the data in Table 2 is not consistent with the conclusion reached. As understood in the art of enzymology a substrate is what the enzyme acts upon. A substance can be a substrate for more than one enzyme depending on activity and specificity. In the instant case, the substrates are all  $\beta$ -D-galactopyranoside derivatives as set forth at page 5 of the disclosure. That is, the glycon is the same and the aglycon changes. Such substances are substrates for  $\beta$ -galactosidase, an enzyme that is known in the art to be relatively promiscuous for the aglycon as long as it is large and hydrophobic. Many aromatic chromogenic and fluorogenic substrates for this enzyme are known, some of which are the same as those instantly disclosed. Each of these substrates has different catalytic rate constants with galactosidase resulting from well-understood phenomena (such as a Hammett plot). The work of Sinnott and coworkers have examined many such substrates (see Sinnott et al. (1978) **FEBS Lett.**, **94**, 1, for example.) Contrary to the assertion that some of these substrates are acted upon by one organism and not another, if the same enzyme is present, they must all be acted upon, albeit at different rates. The only evidence proffered is slightly different colors for the non-target bacteria. This is

not evidence of lack of activity, only evidence of different degrees of conversion, due to different specificity for the substrates by  $\beta$ -galactosidase from different organisms. It is virtually unheard of that the same enzyme from different species would not act at all on substrates having the same specificity factor, in this case, the glycon,  $\beta$ -D-galactose.

***Claim Rejections - 35 USC § 103***

Claims 1-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Monget et al. (USPN 5,434,056).

It is argued that the new claims distinguish over Monget et al. in requiring some of the non-target organism react with a first substrate but not the second, and some react with the second and not the first.

As discussed above, this limitation is not well taken. Further, the specification does not provide explicit support for the limitation. Regardless, the question is whether it is obvious to use more than one chromogenic substrate for the non-target bacteria that meet the new limitation.

The previous Office action established that it was *prima facie* obvious to use more than one chromogenic/fluorogenic substrate for the non-target bacteria, which has not been challenged. Instead, a new limitation was added. The instant disclosure provides a single example of a combination of two substrates: 5-bromo-4-chloro-3-indoxyl-beta-D-galactopyranoside and 3-indoxyl-beta-D-galactopyranoside in Table 1. These two are drawn from the list of possible compounds at page 5 of the disclosure. There is no evidence of corresponding results being obtained from other combinations of substrates from the list at page 5, or that the results obtained are particularly unexpected. Since, nearly the same suite of

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substrates are listed in Monget et al., it is reasonable to assume that if it is obvious to combine any two substrates, and any two substrates are alleged to provide the instant results, then it is obvious that the combination of any two substrates from Monget et al. will give corresponding results.

Applicant's arguments filed 15 August 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

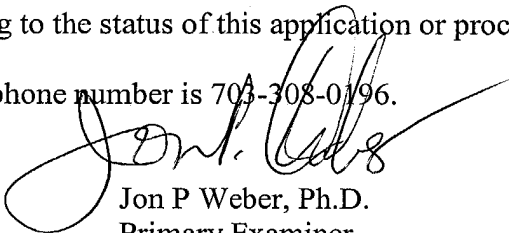
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015.

The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
20 October 2003